

COMMENT

THE CASE AGAINST TRIPS-PLUS PROTECTION IN DEVELOPING COUNTRIES FACING AIDS EPIDEMICS

CHARLES T. COLLINS-CHASE*

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* J.D. Candidate 2008, University of Pennsylvania Law School; M. Phil. 2005, University of Cambridge; B.S. 2004, University of Delaware. I'd like to thank Professor Osagie Imasogie for his thoughtful comments on this piece, as well as the dedicated staff of the University of Pennsylvania Journal of International Law. Finally, I'd like to thank my family for their encouragement and support. All errors are mine alone.

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1. INTRODUCTION

It is commonly held that patents are a crucial factor in spurring development of new technologies, and must be protected even if doing so prevents access by those who need the technology most. Yet the preference for protection over access is not universal, particularly when the product at issue relates to human health. For example, many scholars believe that intellectual property ("IP") protection should not be a barrier to distribution of pharmaceuticals in areas facing a human health crisis. The greatest conflict between IP protection and human health occurs when a nation or region faces a severe health emergency but the average person cannot afford access to essential medicines. The World Trade Organization's ("WTO") Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS")¹ tries to mitigate this tension, offering flexibilities in IP protection when necessary to safeguard human health.

¹ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex IC, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 319, 33 I.L.M. 1125, 1197 (1994) [hereinafter TRIPS Agreement].

However, the TRIPS Agreement merely sets minimum standards of intellectual property rights, and countries are free to negotiate and bind themselves to more stringent IP regimes. Developed countries that export a great deal of intellectual property—in particular the United States—pursue a policy of negotiating bilateral free trade agreements (“FTAs”) that require IP protection far in excess of TRIPS-mandated standards, termed “TRIPS-plus” FTAs. In recent years, the United States has been negotiating bilateral TRIPS-plus agreements with both Thailand and the South African Customs Union² (“SACU”) that would include significant changes to these countries’ current IP systems and would far surpass the level of protection set out in the TRIPS Agreement.

Frequently, the stronger intellectual property terms included in TRIPS-plus FTAs have a significant impact on a nation’s access to life-saving medicines, such as AIDS antiretrovirals, by limiting the nation’s ability to use public health flexibilities under TRIPS. This is a significant concern in Thailand and the SACU countries because of the HIV/AIDS epidemic in Southeast Asia and sub-Saharan Africa. These TRIPS-plus agreements warrant close scrutiny to determine if the consequences of such strong patent protection in the pharmaceutical field, and the attendant decreases in flexibility to address human health concerns, are economically or socially warranted by increases in foreign direct investment or GDP growth.

After analyzing the terms of the Thailand and SACU FTAs and some anticipated consequences, this Comment will compare them to the bilateral FTA that the United States completed with Australia in 2004. This comparison gives particularly useful insights because Australia has a prescription drug program that shares some features in common with the governmental provision of pharmaceuticals in Thailand and the SACU countries. This comparison is also useful because the SACU countries and Thailand both face a significant AIDS problem and lack pharmaceutical manufacturing capacity, and are likely to experience more adverse effects than Australia, which can thus provide a baseline of the negative consequences of these two proposed FTAs. This comparison should illustrate the potential economic results for Thailand and SACU and also permit general

² The South African Customs Union (“SACU”) countries are South Africa, Botswana, Lesotho, Namibia, and Swaziland.

recommendations for developing countries with severe HIV/AIDS problems as they consider FTAs with the United States or other industrialized countries.

2. THE HIV/AIDS EPIDEMIC

2.1. *The Nature of the Problem*

HIV and AIDS are widely recognized as a growing problem of paramount importance.³ According to the World Health Organization ("WHO") and the Joint United Nations Programme on HIV/AIDS ("UNAIDS"), in 2007, 33.2 million people worldwide were living with HIV and roughly 2.5 million people were newly infected.⁴

The HIV/AIDS problem is the most acute in developing countries. In 2002, roughly 36 million people in the developing world had HIV/AIDS.⁵ The region most severely affected is sub-Saharan Africa, where in 2007 there were 22.5 million people living with HIV,⁶ or 68% of the global total.⁷ It is not only the total number of people infected that is alarming—adult HIV prevalence is also staggeringly high. According to recent population-based HIV surveys, in 2005–06, Zimbabwe had an adult prevalence rate of 18.1%.⁸ In 2004, Botswana had a rate of 25.2% and Lesotho's rate

³ While diseases such as malaria and tuberculosis are also prevalent and deadly in the developing world, both the extent of the epidemic and the lack of access to treatment are more pronounced in the case of HIV/AIDS. As such, this Comment is limited to that disease and its treatment.

⁴ See JOINT U.N. PROGRAMME ON HIV/AIDS & WORLD HEALTH ORG., AIDS EPIDEMIC UPDATE at 1, U.N. Doc. UNAIDS/07.27E/JC1322E (2007), available at http://data.unaids.org/pub/EPISlides/2007/2007_epiupdate_en.pdf [hereinafter 2007 AIDS EPIDEMIC UPDATE] (summarizing both global and regional HIV/AIDS statistics). Estimates of the total number of people worldwide living with HIV fell from 2006 to 2007 due to advances in the methodologies used to estimate infected people. *Id.* at 3. This drop was largely due to a major revision of the totals estimated for India. *Id.* Roughly 70% of the changed estimate is due to new data for India, Angola, Kenya, Mozambique, Nigeria, and Zimbabwe, none of which is a SACU nation. *Id.*

⁵ See WORLD HEALTH ORG., SCALING UP ANTIRETROVIRAL THERAPY IN RESOURCE-LIMITED SETTINGS: GUIDELINES FOR A PUBLIC HEALTH APPROACH, EXECUTIVE SUMMARY 8 (2002) [hereinafter SCALING UP ANTIRETROVIRAL THERAPY] (noting growing problems of access to new HIV/AIDS medications in developing countries and offering guidelines for improvement).

⁶ 2007 AIDS EPIDEMIC UPDATE, *supra* note 4, at 7.

⁷ *Id.* at 15.

⁸ *Id.* at 11.

was 23.5%, while a 2006–07 survey in Swaziland showed a prevalence of 25.9%.⁹

After sub-Saharan Africa, the second highest number of cases occurs in Southeast Asia. The WHO estimates that 7.2 million people in the region were living with HIV/AIDS in 2006.¹⁰ Thailand is particularly interesting because it is badly afflicted by HIV/AIDS, but has instituted successful programs to combat the disease. As an indication of progress, the number of new HIV infections in Thailand decreased 10% from 2004 to 2005.¹¹ Despite this improvement, the country still has 580,000 infected people,¹² and a large number of new infections are occurring in people considered to have a low risk of infection, such as married women.¹³ In addition, HIV prevalence is very high for specific subgroups in Thailand, ranging from 30% to 50% for injecting drug users over the past fifteen years.¹⁴

The advance of AIDS shows few signs of slowing, and again the developing world accounts for the vast majority of new cases. Sub-Saharan Africa had 1.7 million new HIV infections in 2007 alone,¹⁵ while South and Southeast Asia accounted for 860,000 new cases in 2006.¹⁶ In 2006, new HIV infections in these two regions totaled 3.66 million (roughly 85%) of the 4.3 million new cases worldwide.¹⁷

The severity of the HIV/AIDS epidemic in the developing world is made clear by comparison to North America and Western and Central Europe, where 2.1 million people were living with HIV/AIDS in 2006, and 78,000 new people were infected in 2007.¹⁸

⁹ *Id.*

¹⁰ WORLD HEALTH ORG., HIV/AIDS IN THE SOUTH-EAST ASIA REGION 4 (2007), available at http://www.searo.who.int/LinkFiles/AIDS_SEARO-Report07.pdf. Note that this report reflects updated numbers for India based on the new methodologies discussed in note 4.

¹¹ JOINT U.N. PROGRAMME ON HIV/AIDS & WORLD HEALTH ORG., AIDS EPIDEMIC UPDATE 32–33 (2006), available at http://www.who.int/hiv/mediacentre/2006_EpiUpdate_en.pdf [hereinafter 2006 AIDS EPIDEMIC UPDATE].

¹² WORLD HEALTH ORG., EPIDEMIOLOGICAL FACT SHEETS ON HIV/AIDS AND SEXUALLY TRANSMITTED INFECTIONS: THAILAND 2 (2006), available at http://www.searo.who.int/LinkFiles/Facts_and_Figures_EFS2006_TH.pdf.

¹³ 2006 AIDS EPIDEMIC UPDATE, *supra* note 11, at 33.

¹⁴ 2007 AIDS EPIDEMIC UPDATE, *supra* note 4, at 25.

¹⁵ *Id.* at 15.

¹⁶ 2006 AIDS EPIDEMIC UPDATE, *supra* note 11, at 2.

¹⁷ *Id.*

¹⁸ 2007 AIDS EPIDEMIC UPDATE, *supra* note 4, at 33.

To put these numbers in context, in 2007 North America had an adult prevalence of only 0.6% while Western and Central Europe had an adult prevalence of 0.3%, both below the global rate of 0.8% and far below the rates in sub-Saharan Africa and Southeast Asia.¹⁹

2.2. Antiretroviral Treatment

While antiretroviral drugs ("ARVs") are not a cure, they are an effective way to treat HIV/AIDS. One physician stated that ARVs "improve patients' lives and help them to resume their daily activities. Patients also have a better immune system and have better resistance to opportunistic diseases."²⁰ The WHO reports that ARVs have "dramatically improved rates of mortality and morbidity, prolonged lives, improved quality of life, revitalised communities and transformed perceptions of HIV/AIDS from a plague to a manageable, chronic illness."²¹ By some estimates, over 200,000 AIDS deaths each year in South Africa alone are preventable with ARVs.²² Great need exists for ARVs. In 2005, the WHO estimated that 4.7 million people in the African region needed antiretrovirals.²³

Despite the efficacy of and tremendous need for ARV treatment, many HIV/AIDS-infected people in the developing world do not have access to these essential medicines. In 2003, of the roughly five to six million people who urgently needed ARVs worldwide, only about 400,000 actually had access to them.²⁴

While many factors contribute to unavailability of medicines, in large part the access gap can be attributed to the cost of treatment. For example, in South Africa, a three-drug ARV treatment costs \$2000 per person each year at private sector wholesale prices and

¹⁹ *Id.* at 7.

²⁰ OXFAM INT'L, BRIEFING PAPER NO. 86, PUBLIC HEALTH AT RISK 6 (2006) (quoting Dr. Janjira Jirtaknatee).

²¹ SCALING UP ANTIRETROVIRAL THERAPY, *supra* note 5, at 8.

²² Sean Flynn, *Legal Strategies for Expanding Access to Medicines*, 17 EMORY INT'L L. REV. 535, 540 (2003) (citations omitted).

²³ WORLD HEALTH ORG., HIV/AIDS EPIDEMIOLOGICAL SURVEILLANCE REPORT FOR THE WHO AFRICAN REGION: 2005 UPDATE 1 (2005), available at http://www.who.int/hiv/pub/epidemiology/hivinafrica2005e_web.pdf.

²⁴ FREDERICK M. ABBOTT & RUDOLPH V. VAN PUymbroeck, COMPULSORY LICENSING FOR PUBLIC HEALTH: A GUIDE AND MODEL DOCUMENTS FOR IMPLEMENTATION OF THE DOHA DECLARATION PARAGRAPH 6 DECISION 1 (2005) (citing UNAIDS, 2004 REPORT ON THE GLOBAL AIDS EPIDEMIC 101 (2004)).

\$750 for the public sector.²⁵ However, the median yearly household income in South Africa is only \$1000²⁶—much too little to afford ARV treatment using brand name medicines, and in most cases insufficient to afford the cost in the public sector. As a result of this and other factors, developing countries, which comprise 75% of the global population, account for less than 10% of the global pharmaceutical market.²⁷

One solution to the access problem is development of less expensive, generic forms of patented drugs. The term “generics” refers both to drugs produced after patent protection has expired and to drugs whose production during the patent term is authorized by a licensing agreement. Generics often have the same or similar efficacy as brand-name drugs at a lower price. The price differential may be significant, and generics can greatly expand access. For example, the drug fluconazole, used to treat HIV, costs \$20 per day in Kenya, where it is protected by patent. A generic version of the same drug costs only 70 cents per day in Thailand.²⁸

3. THE TRIPS AGREEMENT FRAMEWORK

The subject of intellectual property often stirs passionate debate within the context of the pharmaceutical industry, especially in regions afflicted with HIV/AIDS. The World Trade Organization’s TRIPS Agreement, enacted in 1994, sets minimum standards of intellectual property protection required of all WTO member nations.²⁹ The TRIPS Agreement fundamentally altered global patent law by conditioning a member nation’s right to export goods to other members upon enforcement of intellectual property protection. TRIPS expanded protection to several areas where patents previously were not available. For example, before enactment of the TRIPS Agreement, most countries’ IP systems, in developing countries and developed nations alike, at some point

²⁵ Flynn, *supra* note 22, at 540.

²⁶ *Id.* at 541.

²⁷ See Ellen ‘t Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha*, 3 CHI. J. INT’L L. 27, 28 (2002) (discussing the access problem facing developing countries in the pharmaceutical sector).

²⁸ DONALD G. RICHARDS, *INTELLECTUAL PROPERTY RIGHTS AND GLOBAL CAPITALISM* 159 (2004).

²⁹ Exceptions to the TRIPS requirements were made for developing countries, which were not required to come into TRIPS compliance until 2006. That deadline was later extended to 2016.

had refused to grant pharmaceutical patents.³⁰ Under TRIPS, pharmaceuticals are subject to patent protection in all WTO nations.³¹

The TRIPS Agreement has several other patent provisions with implications in the pharmaceutical context. First, Article 28 allows pharmaceutical companies to control the location of production, stating that patent holders have the right to exclude others from “making, using, offering for sale, selling, or importing” its patented products.³² Article 28 could potentially impede the ability of developing countries to produce essential medicines locally. Second, Article 39.3 protects undisclosed test data or other information related to pharmaceuticals from unfair commercial use and disclosure.³³ This provision may be interpreted to extend protection of pharmaceutical products—even beyond their twenty-year patent term—by protecting the data that led to their creation.

3.1. Flexibilities Under TRIPS

The TRIPS Agreement’s minimum standards significantly reduced developing countries’ options for getting access to

³⁰ Simon Walker, *The TRIPS Agreement, Sustainable Development and the Public Interest* 23 (IUCN Environmental Policy and Law Paper No. 41, 2001), available at http://www.ecolomics-international.org/iprsan_simon_walker_iucn_trips.pdf.

³¹ See TRIPS Agreement art. 27.1 (stating that “patents shall be available for any inventions” and that patents shall be “enjoyable without discrimination as to . . . the field of technology”).

³² TRIPS Agreement art. 28.1(a). Article 28 has led to some movement of pharmaceutical production out of developing countries. See Brook K. Baker, *Analysis and Response to WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* 10 n.18 (United Nations Millennium Development Goals Project Task Force 5, Dec. 10, 2003) (noting that Chile and South Africa lost pharmaceutical facilities shortly after the adoption of the TRIPS Agreement). This is in spite of the goal of technology transfer to developing countries, stated in Article 7. See TRIPS Agreement art. 7 (“The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology . . .”).

³³ Article 39.3 of the TRIPS Agreement states:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

essential medicines. However, the agreement retains an emphasis, at least in principle, on promoting human health. Article 8 states that members may implement measures needed to protect public health as long as those measures are consistent with the other provisions of TRIPS.³⁴ Despite strong IP protection, several key areas of flexibility remain in TRIPS that should help these countries protect public health. These include compulsory licensing, parallel importation, provisions defining the scope of patentable subject matter, the early working exception and provisions regarding the extent of test data protection, and measures to control abuse of patent rights and anticompetitive practices.³⁵ The main features of these flexibilities are addressed here.

3.1.1. *Compulsory Licensing*

Many countries, including developed nations, offer some form of compulsory license under their patent system.³⁶ These licenses are created without the permission of the patent holder, and are generally made available to address problems or inequities in the patent system, such as anticompetitive practices or public health emergencies.³⁷ While actual use of compulsory licensing has been rare, the threat of this measure occasionally has been effective in addressing public health emergencies. For example, both the United States and Canadian governments used the threat of

³⁴ See TRIPS Agreement art. 8.1 ("Members may . . . adopt measures necessary to protect public health . . . provided that such measures are consistent with the provisions of this Agreement.").

³⁵ See, e.g., SISULE F. MUSUNGU ET AL., SOUTH CENTRE, UTILIZING TRIPS FLEXIBILITIES FOR PUBLIC HEALTH PROTECTION THROUGH SOUTH-SOUTH REGIONAL FRAMEWORKS 12-23 (2004), available at <http://www.southcentre.org/publications/flexibilities/flexibilities.pdf>.

³⁶ See CARLOS CORREA, SOUTH CENTRE, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES 93 (2000), available at <http://www.southcentre.org/publications/publichealth/publichealth.pdf> (citation omitted) [hereinafter CORREA, INTEGRATING PUBLIC HEALTH CONCERNS] (defining "compulsory licenses" and discussing the grounds for granting a compulsory license); MUSUNGU ET AL., *supra* note 35, at 13 (listing situations where compulsory licenses are an appropriate tool). See generally Carlos M. Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* (South Centre, Trade-Related Agenda, Development and Equity, Working Paper 5, Oct. 1999), available at <http://www.southcentre.org/publications/workingpapers/wp05.pdf> (discussing conditions that may give rise to authorization for compulsory licenses, including, *inter alia*, refusal to deal, non-working and inadequate supply, public interest, and anticompetitive practices).

³⁷ CORREA, INTEGRATING PUBLIC HEALTH CONCERNS, *supra* note 36, at 94.

compulsory licenses to spur Bayer, the holder of the patent on the antibiotic drug ciprofloxacin ("Cipro"), to make sufficient quantities to respond to the anthrax scare that followed the September 11, 2001 attacks.³⁸

Article 31 of the TRIPS Agreement permits member nations to issue compulsory licenses of patented products, and while it does not technically restrict the grounds on which members may grant licenses, it does set out conditions that member states should meet.³⁹ For example, members should only grant compulsory licenses on a case-by-case basis.⁴⁰ Compulsory licenses are only permitted where a member has tried to get a license from the patent holder on "reasonable terms and conditions," but these efforts have been unsuccessful.⁴¹ However, this prior request condition may be waived in the case of a "national emergency" or other extremely urgent situation, if use is non-commercial.⁴² Importantly, the term of use under the compulsory license is limited to "the purpose for which it was authorized" under Article 31(c).⁴³ Further, authorization under the compulsory license can be terminated when the circumstances that justified the use cease to exist.⁴⁴

Another important condition is that the compulsory license must be used "predominantly for the supply of the domestic market"⁴⁵ This requires that at least 50% of the product that is manufactured be used domestically. This condition has serious implications for countries that do not have pharmaceutical manufacturing capacity because they may not be able to meet this requirement, and TRIPS limits other nations' ability to export medicines to the country in need under the terms of a compulsory license.

Finally, the patent holder has the right to compensation for the

³⁸ See Baker, *supra* note 32, at 13 (discussing U.S. and Canadian threats of a compulsory license for ciprofloxacin).

³⁹ TRIPS Agreement art. 31 (discussing the requirements for issuing a compulsory license).

⁴⁰ See *id.* art. 31(a) ("[A]uthorization of such use shall be considered on its individual merits.")

⁴¹ *Id.* art. 31(b).

⁴² *Id.*

⁴³ *Id.* art. 31(c).

⁴⁴ *Id.* art. 31(g).

⁴⁵ *Id.* art. 31(f).

use based on the economic value of the license.⁴⁶ Interestingly, the remuneration requirement applies even when a product is exported to a country where it is not protected by a patent. In these circumstances, the importing country is worse off under TRIPS than if it fostered domestic production of products that were patented abroad, but not subject to patent protection domestically.⁴⁷

3.1.2. *Parallel Importation*

The second key flexibility in TRIPS is parallel importation, which is closely coupled with compulsory licensing. This term refers to a practice in which a third party imports a product marketed in a foreign country by the patent holder, in competition with the product that same patent holder imports or manufactures locally.⁴⁸ This practice is used to prevent price discrimination between markets in cases where a product is available at a much lower price in one country than in another.⁴⁹ Supporters of parallel importation point out that patent holders still receive compensation in the country in which the product is first sold. Parallel imports are allowed under TRIPS Article 8.1.⁵⁰

3.1.3. *Research and Early Working Exceptions, Test Data Limitations*

An effective way to speed introduction of less expensive generic medicines is to allow development prior to expiration of the patented drug's protection. The research and experimental use exception allows manufacturers of generics to experiment with patented drugs during the patent term to try to "invent around" the patent.⁵¹ This can lead to new products that serve the same

⁴⁶ *Id.* art. 31(h).

⁴⁷ See Baker, *supra* note 32, at 26 ("[T]he importing, no-patent Member will be required to pay the added cost of a license royalty even though there would have been no royalty on locally produced medicines.").

⁴⁸ See MUSUNGU ET AL., *supra* note 35, at 13 (discussing parallel importation under the TRIPS Agreement).

⁴⁹ *Id.* at 14.

⁵⁰ See TRIPS Agreement art. 8.1 ("Members may... adopt measures necessary to protect public health and nutrition..."). For a more thorough discussion of the benefits, drawbacks, and legal basis for parallel importation, see CORREA, INTEGRATING PUBLIC HEALTH CONCERNS, *supra* note 36, at 71-80.

⁵¹ See MUSUNGU ET AL., *supra* note 35, at 17 ("The exception is useful in fostering pharmaceutical technological progress by exempting experimentation

purposes as the patented invention, or to improvements on the existing patent.⁵² This exception falls under TRIPS Article 30,⁵³ and also exists in the United States although its scope is somewhat narrow.⁵⁴

The early working exception allows makers of generics to use a patented drug without permission from the patent holder in order to produce and then obtain regulatory approval and registration of a generic before the patent drug's term of protection expires.⁵⁵ However, the generic is not released in the market before expiry of the patent term. Instead, the exception helps ensure that generics are available without significant delay following expiration of the patent term.⁵⁶ In the United States, this exception is codified in the 1984 Drug Price Competition and Patent Term Restoration Act,⁵⁷ also called the Hatch-Waxman Act. It is also called the "Bolar" exception.⁵⁸

Finally, flexibility regarding protection of test data stems from

acts for purposes such as inventing around the initial invention, improving on the invention or for the purposes of evaluating the invention and determining if it works.").

⁵² CORREA, INTEGRATING PUBLIC HEALTH CONCERNS, *supra* note 36, at 66 ("An experimental use exception may foster technological progress based on 'inventing around' or improving a protected invention, as well as permit evaluation of an invention . . .").

⁵³ See TRIPS Agreement art. 30 ("Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent . . ."). Experimental use is allowed under TRIPS Article 30, but because in practice it may lead to creation of products that are very similar to patented ones, it may give rise to infringement under the doctrine of equivalents in some countries. See CORREA, INTEGRATING PUBLIC HEALTH CONCERNS, *supra* note 36, at 66, 87-91 (discussing patent infringement through equivalence).

⁵⁴ See CORREA, INTEGRATING PUBLIC HEALTH CONCERNS, *supra* note 36, at 66 (citing HAROLD WEGNER, PATENT LAW IN BIOTECHNOLOGY, CHEMICALS AND PHARMACEUTICALS 267 (1994)).

⁵⁵ See MUSUNGU ET AL., *supra* note 35, at 17-18 (explaining that the purpose of the early working exception was to ensure that generic versions would be available on the market within a reasonable time of the patent expiration).

⁵⁶ *Id.*

⁵⁷ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.).

⁵⁸ The "Bolar" exception is named for the case *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984) (holding that that the competitor's use of a patented ingredient to perform tests necessary for FDA approval for its own product was infringement because it did not fall within the experimental use exception).

interpretation of TRIPS Article 39.3, which states that when a member nation mandates submission of undisclosed test data as a condition of market approval for new pharmaceuticals or other new chemicals, the member nation must protect against unfair commercial use of this data.⁵⁹ However, the text also says that member nations shall protect against disclosure of this data except where it is necessary to protect the public.⁶⁰ Some scholars argue that requiring generic drug manufacturers to conduct the same tests as the holder of a drug patent, at considerable expense, increases generic prices and decreases the social utility of generics.⁶¹

3.2. *Benefits of TRIPS Flexibilities and Generics*

The provisions in TRIPS designed to protect public health, such as compulsory licenses, can have a significant impact. For example, in Brazil between 1996 and 2000, AIDS drugs with no generic substitutes saw only a 9% price drop.⁶² However, Brazil instituted its own Industrial Property Law ("IPL") in 1997, which made patent protection contingent on production of the patented items in Brazil (termed "local working") and also provided for compulsory licenses of products not produced locally if they are sufficiently important.⁶³ As a result, the price of drugs with generic substitutes fell 79% from 1996 to 2000.⁶⁴ Thailand has also pursued a successful strategy for treating its HIV/AIDS problem based on the use of generic drugs, discussed further in Section 6.1, *infra*.

⁵⁹ TRIPS Agreement art. 39.3.

⁶⁰ See *id.* ("Members shall protect such data against disclosure, except where necessary to protect the public . . .").

⁶¹ See Frederick M. Abbott, *The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference* 29 (United Nations Quaker Office, Occasional Paper No. 7, 2001) [hereinafter Abbott, *Access to Medicines*] ("Requiring generic producers to conduct identical trials on equivalent compounds is socially wasteful and imposes additional costs on the public.").

⁶² RICHARDS, *supra* note 28, at 159.

⁶³ *Id.* at 157.

⁶⁴ *Id.* at 159.

4. RESPONSES TO TRIPS

4.1. U.S. Action

Despite the strong protection for intellectual property rights given by TRIPS, developed countries, notably the United States and the European Union, have sought even stronger patent protection. This was a response, in part, to use by developing nations of the flexibilities within TRIPS to promote public health. For example, when the government of Thailand sought to produce generic forms of patented drugs under the compulsory licensing provision of TRIPS, the United States threatened trade sanctions through the U.S. Trade Representative ("USTR").

The United States pursued similar tactics in South Africa. In 1997, the South African government introduced the Medicines Act, a bill that allowed parallel importation of patented HIV/AIDS drugs.⁶⁵ As a result, the USTR listed South Africa for possible sanctions if it did not abandon the bill.⁶⁶ In 1998, a group of pharmaceutical companies brought suit against the South African government in the South African courts, alleging that the Medicines Act discriminated against pharmaceutical producers in violation of the nation's obligations under TRIPS.⁶⁷ Only under the intense pressure of an international lobbying effort against them did these companies drop their lawsuit.⁶⁸

4.2. The Doha Declaration

In April 2001, developing countries responded to the positions taken by developed countries such as the United States. Zimbabwe, acting on behalf of the Africa Group, demanded that

⁶⁵ See PETER DRAHOS, EXPANDING INTELLECTUAL PROPERTY'S EMPIRE: THE ROLE OF FTAs 16 (2003), available at http://www.grain.org/rights_files/drahos-fta-2003-en.pdf [hereinafter DRAHOS, ROLE OF FTAs] ("[The Medicines Act] specifically allowed the importation into South Africa of patented medicines which had been put onto another market with the consent of the patent owner. The idea was to encourage the importation of patented medicines from the cheapest market (parallel importation) . . .").

⁶⁶ *Id.*

⁶⁷ See *id.* at 16 ("[I]n February of 1998, 41 pharmaceutical companies began proceedings in South African courts against the South African government, naming Nelson Mandela as first defendant.").

⁶⁸ See *id.* at 17 ("In April of 2001 the pharmaceutical companies withdrew from the litigation because of a highly effective global public campaign by civil society.").

the TRIPS Council hold a special session to discuss access to medicines. The United States and European Union took strong stances in their submissions to the TRIPS Council, advocating strong patent rights. The United States argued that strong patent protection promotes research and development on new pharmaceutical products, encourages foreign direct investment, and promotes disclosure of technical knowledge.⁶⁹ The United States also argued that least developed WTO member countries should show evidence that they would be harmed by strong patent protection before any extension should be granted to the timetable for compliance with TRIPS.⁷⁰

Developing countries also advocated strong positions. They asserted that patents on pharmaceuticals raise prices and decrease access; that developing nations should be able to use the flexibilities within TRIPS without the threat of trade sanctions from developed countries; that least developed countries ("LDCs") needed an extension beyond 2006 to come into TRIPS compliance; that developing countries needed to be able to get generic medicines from exporting countries; and that the data protection rules in TRIPS Article 39.3 should not be used to prevent registration of generics.⁷¹ Developing countries proposed that TRIPS should include text stating, "[n]othing in the TRIPS Agreement shall prevent Members from taking measures to protect public health."⁷²

Despite widely divergent positions, the developed and developing countries eventually reached agreement on access to medicines. At the Fourth WTO Ministerial Conference, held in Doha, Qatar, in November 2001, the WTO members adopted the

⁶⁹ See Abbott, *Access to Medicines*, *supra* note 61, at 4 (laying out the United States' arguments for strong patent protection).

⁷⁰ *Id.*

⁷¹ See Council for Trade-Related Aspects of Intellectual Property Rights, *TRIPS and Public Health: Submission by the African Group et al.*, at 3–4, IP/C/W/296 (June 29, 2001) (describing Resolution 200/33 adopted by the 57th Session of the U.N. Commission on Human Rights, which called upon its members to take measures to safeguard access to preventative, curative, or palliative pharmaceuticals); Council for Trade-Related Aspects of Intellectual Property Rights, *Ministerial Declaration on the TRIPS Agreement and Public Health: Submission by the African Group et al.*, IP/C/W/312 (Oct. 4, 2001) [hereinafter Ministerial Declaration] (recognizing that TRIPS should not limit the research, development, and availability of medicines and treatments).

⁷² Ministerial Declaration, *supra* note 71, at para. 1.

"Doha Declaration."⁷³ It explicitly recognized the severity of the health crises facing developing countries resulting from HIV/AIDS, malaria, tuberculosis, and other diseases.⁷⁴ Most importantly, the Declaration stated that the TRIPS Agreement "does not and should not prevent Members from taking measures to protect public health."⁷⁵ As a result, the Declaration stated that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."⁷⁶

Also significant in the Doha Declaration was the statement that "[e]ach Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstance of extreme urgency."⁷⁷

4.3. Compelling Stronger IP Protection Through TRIPS-Plus Free Trade Agreements

Developed countries have not stopped negotiating for strong patent protection since the Doha Declaration. It is no surprise that developed countries, and particularly the United States, favor strong intellectual property rights. After all, the United States was the world's leading exporter of intellectual property at the time the TRIPS Agreement was signed and continues to benefit greatly from

⁷³ World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration]; World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Declaration on TRIPS & Public Health].

⁷⁴ See Declaration on TRIPS & Public Health, *supra* note 73, at para. 1 ("We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.").

⁷⁵ *Id.* at para. 4.

⁷⁶ *Id.* The emphasis on health is consistent with international law. For example, the Universal Declaration of Human Rights ("UDHR") states that "[e]veryone has the right to a standard of living adequate for the health and well-being of himself and of his family, including . . . medical care and necessary social services . . ." Universal Declaration of Human Rights, G.A. Res. 217A, art. 25, U.N. GAOR, 3d Sess., 1st plen. mtg., U.N. Doc A/810 (Dec. 12, 1948) [hereinafter UDHR].

⁷⁷ Declaration on TRIPS & Public Health, *supra* note 73, at para. 5(c).

intellectual property exports.⁷⁸ The TRIPS Agreement merely sets minimum standards of intellectual property protection, and countries are free to negotiate stronger protection under multilateral or bilateral FTAs. These agreements are termed “TRIPS-plus” because they augment the intellectual property protection available to developed countries existing under TRIPS. This is not to say that TRIPS provides weak protection for developed countries. In fact, some scholars have argued that the TRIPS agreement not only provides protection that is too strong, but further that it is a coercive treaty of adhesion to which developing countries only acceded based on explicit or implied threats of trade sanctions.⁷⁹

Despite the strength of patent protection granted to developed countries under TRIPS, over 130 bilateral and regional free trade agreements, also called “preferential trade agreements,” are in effect, and most have come into force in the last decade.⁸⁰ In recent years, the United States has concluded bilateral TRIPS-plus FTAs with Jordan (2000), Chile (2003), Singapore (2003), Australia (2004), and Morocco (2004), and negotiated CAFTA, a regional FTA between the United States and Central America (2004).⁸¹ The United States is also in the process of negotiating FTAs with Thailand, Bahrain, Andean countries, and the South African Customs Union.⁸² A large number of the FTAs that the United States has negotiated and is currently pursuing are with developing countries. The same is true of EU countries, which

⁷⁸ See DRAHOS, *ROLE OF FTAS*, *supra* note 65, at 2 (“At the time of the negotiations the US as the world’s principal exporter of intellectual property had much to gain from the globalization of intellectual property rights via the trade regime . . .”).

⁷⁹ See Donald P. Harris, *Carrying a Good Joke Too Far: TRIPS and Treaties of Adhesion*, 27 U. PA. J. INT’L ECON. L. 681, 735 (2006) (citing JEFFREY L. DUNOFF ET AL., *INTERNATIONAL LAW NORMS, ACTORS, PROCESS: A PROBLEM-ORIENTED APPROACH* 788 (2002)) (“Developing countries—which ‘had serious dread’ of the United States’ Section 301 bilateralism—were acutely aware that if they did not sign TRIPS, they would have to individually ‘negotiate’ with the United States under threat of Section 301 actions.”).

⁸⁰ GRAIN, “TRIPS-PLUS” THROUGH THE BACK DOOR: HOW BILATERAL TREATIES IMPOSE MUCH STRONGER RULES FOR IPRs ON LIFE THAN THE WTO 8 (2001), *available at* http://grain.org/briefings_files/trips-plus-en.pdf.

⁸¹ See OXFAM INT’L, *UNDERMINING ACCESS TO MEDICINES: COMPARISON OF FIVE U.S. FTAS 1* (2004) [hereinafter *COMPARISON OF FIVE U.S. FTAS*] (listing recent U.S. FTAs).

⁸² *Id.*; Baker, *supra* note 32, at 61 n.141.

have recently completed over thirty Bilateral Preferential Agreements with countries in the Middle East and North Africa.⁸³

Some scholars have suggested that the resistance that the United States and the EU encounter in achieving their trade goals through multinational negotiations dictates the strength with which they pursue an agenda of bilateral TRIPS-plus FTAs.⁸⁴ As a result of strong resistance at the TRIPS Council and at Doha—both multilateral settings—these developed nations have sought agreements that circumvent TRIPS flexibilities and offer stronger patent protection than they could achieve in the TRIPS setting.⁸⁵ This can be seen from several provisions that are common to most recent U.S. TRIPS-plus FTAs. For example, many extend patent protection beyond the maximum twenty-year period set out in both U.S. patent law and TRIPS.⁸⁶ Many also restrict the permissible grounds for compulsory licensing and give patent holders the ability to stop parallel importation.⁸⁷ Finally, these FTAs limit data access for manufacturers seeking to use a patent holder's clinical test data to obtain faster approval for generics, and also prevent registration of generics until after the original drug patent expires.⁸⁸ These provisions of U.S. FTAs specifically address the TRIPS provisions that allow protection of public health in developing countries, and that were specifically reaffirmed in the Doha Declaration.

5. THE CASE AGAINST FTAS IN DEVELOPING COUNTRIES

Developed countries advocate FTAs by highlighting potential increases in foreign direct investment ("FDI") and technology transfer, as well as more trade and greater market access.⁸⁹ In

⁸³ Hamed El-Said & Mohammed El-Said, *TRIPS, Bilateralism, Multilateralism & Implications for Developing Countries: Jordan's Drug Sector*, 2 MANCHESTER J. INT'L ECON. L. 59, 59 (2005).

⁸⁴ See DRAHOS, *ROLE OF FTAS*, *supra* note 65, at 8 ("Where the US or the EU are at any given moment in the cycle of ratcheting [up IP protection] is determined essentially by how much effective resistance they are meeting in terms of their negotiating objectives.").

⁸⁵ See *id.* at 9 ("The [U.S.] focus on FTAs at this time can also be explained in terms of the effective resistance that the US has been encountering at the TRIPS Council over the last several years.").

⁸⁶ COMPARISON OF FIVE U.S. FTAS, *supra* note 81, at 2.

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ See, e.g., RAYMOND J. AHEARN & WAYNE M. MORRISON, *U.S.-THAILAND FREE TRADE AGREEMENT NEGOTIATIONS* 2 (2006), available at <http://www.national>

reality, the economic and social advantages are less clear. First, a great deal of evidence suggests more meager benefits for investment and trade than those touted when FTAs are proposed.⁹⁰ Second, other social and economic costs may partially offset benefits. For example, in countries with significant HIV/AIDS epidemics, limiting flexibilities to address this public health issue may have negative economic effects.⁹¹ Finally, developing countries must also take account of negative economic impacts caused by trade sanctions, such as USTR 301 actions, that may accrue if they do not agree to heightened IP protection in an FTA. This balance is highly dependent on characteristics of a particular country and varies a great deal across different industries.

5.1. *The Unrealized Promise of Increased Foreign Direct Investment and Technology Transfer*

A common rationale used to justify strong protection of foreign patents in developing countries is that strong patent rights will increase FDI.⁹² As proof that IP protection is a major factor in drawing and keeping FDI, these scholars point to several visible examples of companies withdrawing investment in developing countries in the face of what they term weak intellectual property protection, or companies investing only after IP laws are strengthened.⁹³ However, even supporters of this theory realize that factors other than a country's intellectual property regime also play a role, including "government regulations, tax policies, and land and labor costs"⁹⁴

This view of the relationship between intellectual property rights and FDI is far from universal. Many scholars argue that

aglawcenter.org/assets/crs/RL32314.pdf (stating that a U.S.-Thailand FTA can increase U.S. investment in Thailand and help "increase the competitiveness and market share of Thai products in the U.S. market").

⁹⁰ See *infra* Section 5.1.

⁹¹ See *infra* Section 6.2.

⁹² See, e.g., David Hindman, *The Effect of Intellectual Property Regimes on Foreign Investments in Developing Economies*, 23 ARIZ. J. INT'L & COMP. L. 467, 474 (2006) (stating that FDI may decrease if developing countries do not implement strong intellectual property protection because "[f]oreign investment entrepreneurs struggle with valuing the risk of investing in a developing country with poor IP enforcement").

⁹³ See *id.* at 473 (discussing the decision by Microsoft to move capital into Brazil after the country enacted new laws for copyright and software protection in 1998, and similar decisions by Canon and Sony).

⁹⁴ *Id.* at 475.

increasing domestic protection for foreign intellectual property does little to boost FDI in developing countries.⁹⁵ A 1993 report by the United Nations Transnational Corporations and Management Division⁹⁶ found little empirical evidence of a correlation between intellectual property rights and FDI. While highly technical industries, such as pharmaceuticals, show stronger evidence of such a correlation,⁹⁷ the United Nations study found that countries with weak protection routinely benefited from strong levels of FDI.⁹⁸ High rates of FDI are correlated with countries the United States Trade Representative has placed on its watch list of worst intellectual property rights violators.⁹⁹ Even a Congressional Research Service report on the proposed U.S.-Thailand FTA notes that FDI in Thailand fell from \$3.9 billion in 2001 to an average \$1.5 billion from 2002–05, partly because FDI was lost to China, a country frequently cited as an IP rights violator.¹⁰⁰

It is perhaps more important that whatever FDI does result from stricter intellectual property rights may not be as beneficial as developed countries claim, and does not seem to spur technology

⁹⁵ See, e.g., Keith E. Maskus, *The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer*, 9 DUKE J. COMP. & INT'L L. 109, 128 (1998) ("[S]trong IPRs alone do not sufficiently generate strong incentives for firms to invest in a country."). But see Edwin Mansfield, *Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer* (Int'l Fin. Corp. Discussion Paper No. 19, 1994) (stating that strong intellectual property rights are a significant factor in spurring FDI).

⁹⁶ U.N. TRANSNAT'L CORPS. AND MGMT. DIV., INTELLECTUAL PROPERTY RIGHTS AND FOREIGN DIRECT INVESTMENT, U.N. Doc. ST/CTC/SER.A/24, U.N. Sales No. E.93.II.A.10 (1993) [hereinafter IP RIGHTS AND FDI].

⁹⁷ *Id.* at 6.

⁹⁸ See Frederick M. Abbott, *Commentary: The International Intellectual Property Order Enters the 21st Century*, 29 VAND. J. TRANSNAT'L L. 471, 474 (1996) ("[C]ountries with the weakest levels of IPRs protection . . . over the past decade have routinely been the recipients of the largest net FDI inflows.").

⁹⁹ *Id.*

¹⁰⁰ AHEARN & MORRISON, *supra* note 89, at 4–5. The CRS report also points out that the 2005 USTR "Special 301" report found that Thailand had taken a number of steps in 2004 to increase IP protection. *Id.* at 8. Thus, a shift of FDI from Thailand to China in 2003, where Thailand had strengthened IP protection and China was cited as a frequent violator of IP rights, is contrary to the view that strengthening IP rights attracts more FDI.

It should be noted that while data are available showing the economic impact of trade sanctions, little attention has been given to the economic impact of USTR "Special 301" listing for countries not subject to sanctions. While such data could be important to a developing country's overall assessment of an FTA, analysis of this complex factor is far beyond the scope of this Comment.

transfer to developing countries. For example, Gürak refers to a class of “hidden costs” of FDI and technology transfer, including non-competition clauses and over-pricing imports while under-pricing exports, which diminish the real economic benefits of FDI.¹⁰¹

In addition, the 1993 United Nations report found that transnational companies, especially those in high-technology fields, did not transfer research and development activities to developing countries.¹⁰² The lack of transfer of technical knowledge diminishes the benefits of any FDI. As a result, while patenting rates may rise in developing countries after stronger intellectual property rights are established, foreign patentees hold the vast majority of new patents while patent rates for national residents remain flat.¹⁰³

5.2. *Economic and Social Costs of HIV/AIDS*

Certain developing countries, particularly those in sub-Saharan Africa and Southeast Asia with high HIV/AIDS infection rates, must also balance the costs of an AIDS epidemic against the benefits of an FTA with a developed country. This is an important consideration because, as discussed in Section 3.2, many FTAs preclude the use of intellectual property flexibilities that are crucial policy options for combating the disease. HIV and AIDS are a tremendous economic and social detriment.¹⁰⁴ Increased mortality and morbidity caused by AIDS affect households, businesses, and the public sector.¹⁰⁵ Prevalence of AIDS may also affect political

¹⁰¹ HASAN GÜRAK, HIDDEN COSTS OF TECHNOLOGY TRANSFER: ADVERSE IMPACTS OF PACKAGE DEALS WITH RESTRICTIVE CLAUSES 12-16 (2001), available at http://www.hasmendi.net/makale_gurak/YK_Ec_Review_HiddenCosts.pdf (discussing costs associated with FDI in package deals).

¹⁰² IP RIGHTS AND FDI, *supra* note 96, at 6 (“Most R&D activity undertaken by [transnational corporations] continues to be highly concentrated in their countries of origin or in other industrialized countries, particularly in high-technology fields.”).

¹⁰³ See Lee G. Branstetter et al., *Do Stronger Intellectual Property Rights Increase International Technology Transfer? Empirical Evidence from U.S. Firm-Level Data* 20 (Nat’l Bureau of Econ. Research, Working Paper No. 11516, 2005) (discussing the impact of development on a nation’s patent system).

¹⁰⁴ See generally THE MACROECONOMICS OF HIV/AIDS 41 (Markus Haacker ed., 2004).

¹⁰⁵ Markus Haacker, *HIV/AIDS: The Impact on the Social Fabric and the Economy*, in THE MACROECONOMICS OF HIV/AIDS, *supra* note 104, at 41, 64 [hereinafter Haacker, *Social Fabric*].

decisionmaking, leading to decreased political efficiency and potentially causing political instability.¹⁰⁶

Economic models show that AIDS may also lower both GDP and per capita income. These decreases are due to several factors. First, countries with AIDS epidemics experience a decreased savings rate because residents spend more money on medical care.¹⁰⁷ Second, mortality and morbidity lead to a smaller labor supply, lowering output, and also to a less efficient workforce.¹⁰⁸ Finally, mortality from AIDS destroys any prior investment in human capital, such as schooling and training.¹⁰⁹ Haacker summarized several studies that predicted these effects in South Africa. A 2000 study by ING Barings South African Research estimated a 12.8% decrease in labor supply and 3.1% decline in real GDP by 2010.¹¹⁰ A similar 2001 study by Arndt and Lewis estimated an 8% decline in per capita GDP by 2010.¹¹¹

One major economic impact incorporated by these GDP estimates is the burden on a country's public health care system. The cost of programs both to treat opportunistic diseases associated with AIDS and to provide ARVs can be staggering. For example, South Africa estimated that in 2007 and 2008, its treatment program would cost 4.5 billion rand, or roughly U.S. \$620 million.¹¹² Estimates in sub-Saharan countries for the year 2010 show AIDS treatment programs accounting for between 0.6% of GDP in South Africa to 3.8% of GDP in Lesotho.¹¹³

Personnel costs associated with HIV/AIDS also affect GDP. Haacker categorizes these costs as absenteeism, sick leave, medical benefits, death-related benefits, and the cost of replacing staff

¹⁰⁶ See *id.* at 65 ("One possible consequence is increased political instability, spurred by dissatisfaction with the government in place or with the political process in general.").

¹⁰⁷ *Id.* at 67.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.* at 76 (citing KRISTINA QUATTEK & THEA FOURIE, ING BARINGS: SOUTH AFRICAN RESEARCH, *THE ECONOMIC IMPACTS OF AIDS IN SOUTH AFRICA: A DARK CLOUD ON THE HORIZON* (2000)).

¹¹¹ Channing Arndt & Jeffrey D. Lewis, *The HIV/AIDS Pandemic in South Africa: Sectoral Impacts and Unemployment*, 13 J. INT'L DEV. 427, 439 (2001).

¹¹² See Markus Haacker, *The Impact of HIV/AIDS on Government Finance and Public Services*, in *THE MACROECONOMICS OF HIV/AIDS*, *supra* note 104, at 198, 228 (discussing South Africa's Operational Plan).

¹¹³ *Id.* at 229.

members lost to HIV/AIDS.¹¹⁴ In a country with AIDS-related mortality of two percent, absenteeism and sick leave alone would cut between two and three percent of the total working time of public sector employees.¹¹⁵ AIDS also has a large impact on the private sector. Haacker points out that private firms experience increases in the costs of employee health care, training and recruiting, and death-related benefits.¹¹⁶ In a 2004 survey, 39% of the South African companies that responded stated that HIV/AIDS had increased absenteeism or reduced productivity of their workforce.¹¹⁷

HIV/AIDS has a distinct economic impact, and many developing countries in sub-Saharan Africa and in Southeast Asia are struggling to fight the disease effectively. For these countries, analysis of the benefits of an FTA with restrictive IP provisions must account for losses in GDP, increased personnel costs, and the burden on its healthcare system. The costs of AIDS significantly offset the benefits of FTAs in these countries, especially in light of the failure of many FTAs to generate the level of FDI and technology transfer that was initially promised.¹¹⁸ Empirical evidence from past FTAs and a comparison of the proposed U.S.-Thailand FTA to other recently completed agreements show that when AIDS-related costs are included, the benefits of the FTA are minimal.¹¹⁹

6. PHARMACEUTICALS AND PROPOSED FTAs IN THAILAND AND THE SACU

Thailand and the SACU are particularly important case studies in this area because both have a high rate of HIV/AIDS and also have been negotiating TRIPS-plus FTAs with the United States. The U.S.-Thailand and U.S.-SACU FTAs would preclude many of the abovementioned TRIPS flexibilities that would allow those countries to combat the disease. The following sections analyze AIDS treatment programs and pharmaceutical sectors in Thailand

¹¹⁴ *Id.* at 203.

¹¹⁵ *Id.* at 204.

¹¹⁶ Haacker, *Social Fabric*, *supra* note 105, at 51-52.

¹¹⁷ *Id.* at 57.

¹¹⁸ *See supra* Section 5.1.

¹¹⁹ *See infra* Section 6.

and the SACU countries, as well as the proposed FTAs with the United States.

6.1. Thailand's HIV/AIDS Treatment Program

In its efforts to treat a growing AIDS problem, Thailand initially focused exclusively on prevention of new infections, but soon realized that treating infected people to prolong and improve the quality of their lives was also essential.¹²⁰ The Thai government began to offer ARV treatment and, in 2002, started a national health insurance system covering 95% of the population for a fee of 30 baht, or U.S. \$0.79, per clinical visit.¹²¹ In 2005, the government announced inclusion of ARV treatment in the "30 baht" treatment system.¹²²

The most significant factor in the success of this program has been the availability of inexpensive generic ARV drugs.¹²³ Initially, the program used branded ARV drugs that cost \$10,000 per person each year.¹²⁴ Then, the Government Pharmaceutical Organization ("GPO") developed an ARV cocktail called GPO-vir, a generic product that combined three drugs (*stavudine*, *lamivudine*, and *nevirapine*).¹²⁵ GPO-vir costs \$31 per person per month, much lower than the \$490 per person per month cost of the branded equivalent.¹²⁶

While GPO-vir has been successful, it is not possible for the Thai government to continue using only that ARV cocktail. So-called "first-line" treatments typically become less effective over time as viruses develop resistance to the drugs.¹²⁷ In addition,

¹²⁰ OXFAM INT'L, *supra* note 20, at 9.

¹²¹ *Id.*

¹²² *See id.* (discussing the "30 baht" treatment program).

¹²³ *See id.* at 9–10 (stating that while increased budget allocations for ARVs helped improve public access, inexpensive generic drugs have been the most crucial factor in the program's success).

¹²⁴ *Id.* at 10.

¹²⁵ *See* JAKKRIT KUANPOTH, INT'L CTR. FOR TRADE & SUSTAINABLE DEV., HARMONISATION OF TRIPS-PLUS IPR POLICIES AND POTENTIAL IMPACTS ON TECHNOLOGICAL CAPACITY: A CASE STUDY OF THE PHARMACEUTICAL INDUSTRY IN THAILAND 25 (2006), available at <http://www.iprsonline.org/unctadictsd/docs/Jakkrit-edited%20final%20draft%2001%20Nov%2006.pdf> (discussing GPO's success in the generic pharmaceuticals market).

¹²⁶ OXFAM INT'L, *supra* note 20, at 10.

¹²⁷ *Id.* at 11.

some patients have adverse reactions to *nevirapine*.¹²⁸ The government will need to get access to second-line and third-line treatments in the future, but these were produced more recently and are subject to patent in Thailand. As a result, the second-line treatments recommended by the WHO are expensive. For example, *lopinavir* syrup costs \$310 per bottle, and a *lopinavir-ritonavir* combination costs \$467 for 180 capsules.¹²⁹ By comparison, a generic version produced in India costs just \$156.¹³⁰

While Thailand has not used compulsory licensing in the past, the World Bank reports that the Thai government could use compulsory licensing to reduce second-treatment ARV cost by 90%, which would reduce future budgetary obligations by \$3.2 billion.¹³¹ Significantly, on November 29, 2006, Thailand announced its plans to issue a compulsory license on the ARV drug *efavirenz*.¹³² A letter from twenty-two members of Congress to the U.S. Trade Representative for the region indicates that the United States is pressuring Thailand not to use the license, possibly through threat of trade sanctions.¹³³ In response to the threat of a compulsory license, Merck, the owner of the patent on *efavirenz*, decided to offer price cuts on the drug to Thailand.¹³⁴

However, not all efforts at compulsory licensing in recent months have proved as effective. Thailand also stated its intention to issue a compulsory license on *lopinavir/ritonavir*, another AIDS drug marketed under the name Kaletra by Abbott Laboratories, a

¹²⁸ *Id.*

¹²⁹ *Id.* at 12.

¹³⁰ *Id.*

¹³¹ ANA REVENGA ET AL., THE WORLD BANK, THE ECONOMICS OF EFFECTIVE AIDS TREATMENT: EVALUATING POLICY OPTIONS FOR THAILAND 169 (2006), available at http://www-wds.worldbank.org/external/default/WDSPContentServer/WDSP/IB/2006/09/26/000310607_20060926124315/Rendered/PDF/374490TH0Economics0aids01PUBLIC1.pdf (“[B]y exercising compulsory licensing to reduce the cost of second-line therapy by 90 percent, the government would reduce its future budgetary obligations by US\$3.2 billion discounted . . .”).

¹³² Letter from Rep. Tom Allen et al., Members of U.S. Cong., to Ambassador Susan C. Schwab, U.S. Trade Representative (Jan. 10, 2007), available at <http://www.cptech.org/ip/health/c/thailand/congressional-schwabletter-thailand-10jan06.pdf> [hereinafter Letter to Ambassador Schwab].

¹³³ See *id.* (“We are writing to urge that the United States respect the decision of the Thai government to issue a compulsory license on the AIDS drug *efavirenz*.”).

¹³⁴ See Amy Kazmin & Andrew Jack, *Merck to Offer AIDS Drug Price Cut to Thais*, FIN. TIMES (London), Dec. 1, 2006, at 10.

U.S. company.¹³⁵ In response, Abbott Laboratories decided to withdraw applications for new drugs in Thailand, including a new heat-stable version of Kaletra. While Abbott is under great pressure from health advocacy groups, such as Médecins Sans Frontières,¹³⁶ the company has not relented on pricing as Merck did, and maintains that Thailand “has chosen to break patents on numerous medicines, ignoring the patent system.”¹³⁷ Thailand’s Ministry of Public Health claims that providing ARVs under the compulsory license will save 8,000 lives.¹³⁸ However, it is unclear to what extent resulting actions by pharmaceutical companies such as Abbott Laboratories, including decreased access to future ARV medications, will compromise the overall efficacy of the compulsory licenses. Despite this altercation, it is still possible that it is in Thailand’s best economic and social interests to continue to issue compulsory licenses where necessary to avert human health crises.

6.2. *The Thailand-U.S. FTA*

The FTA that the United States is negotiating with Thailand largely incorporates the strong level of intellectual property rights and corresponding limits on the flexibilities for developing countries discussed in Section 3.1. The FTA would require Thailand to extend protection to previously non-patentable subject matter, including biological processes, genes, gene sequences, and methods of medical treatment.¹³⁹ This extension diminishes Thailand’s freedom to use products in these categories, and may have an impact on the importation and production of pharmaceuticals.

A second key feature of the FTA is that in some instances, Thailand must allow “second use” patents on drugs that already were protected by patent.¹⁴⁰ For example, if a company finds a

¹³⁵ Amy Kazmin & Andrew Jack, *Thailand Confirms Switch to Generic Medicines*, FIN. TIMES (London), Jan. 30, 2007, at 6.

¹³⁶ *Abbott’s Drug Policy Denounced by MSF*, THE NATION (Thailand), Mar. 19, 2007.

¹³⁷ *Abbott Takes a Tranquilliser, Tells Thais: ‘Talk to My Boss,’* THE NATION (Thailand), Mar. 25, 2007.

¹³⁸ *Id.*

¹³⁹ KUANPOTH, *supra* note 125, at 14.

¹⁴⁰ *Id.* at 15 (“Thailand must allow claims to a new use of an old drug or claims to a new therapeutic application of a known drug.”).

new clinical use for a drug that was already patented and new clinical trials are needed to get marketing approval, the FTA requires three additional years of patent protection.¹⁴¹

The Thailand FTA goes even farther than other FTAs to protect test data. It protects all information relating to a drug, so unlike other FTAs such as CAFTA, protection is not limited to undisclosed data.¹⁴² The FTA also requires Thailand's regulatory body to inform a pharmaceutical patent holder whenever another company seeks registration of a generic drug.¹⁴³ The authority would not be permitted to issue registrations for any generic medicine unless it is sure the drug does not infringe any patents.¹⁴⁴ This provision essentially transforms the Thai regulatory authority into a defender of foreign patent rights.

The Thailand FTA also significantly erodes the availability of compulsory licenses. Thailand would be permitted to issue a license only in certain cases, namely, limiting anticompetitive practices, public non-commercial use, and national emergencies.¹⁴⁵ This protection goes beyond TRIPS, under which there are no restrictions on the circumstances in which a compulsory license may issue provided that the requisite conditions are met.

The United States advocates for the FTA by citing broad economic benefits for both countries. The 2003 Congressional Research Service report speculates that by eliminating U.S. tariff and non-tariff barriers to Thai exports, the FTA could make Thai products more competitive in the U.S. market.¹⁴⁶ This report also

¹⁴¹ See OXFAM INT'L, *supra* note 20, at 19 ("Three additional years of monopoly protection are granted to the company of origin if it finds a new clinical use for a drug already on the market in some form and if new clinical trials are needed to gain marketing approval for the new use (for example, use by children).").

¹⁴² See *id.* at 18–19 (detailing the stringent requirements of the Thailand FTA with respect to test data, and noting that "even clinical trials published in US scientific journals could not be used by the Thai regulatory authority, as it often does now, to register a generic drug"). Preventing use of disclosed test data strengthens protections under the Thailand FTA beyond those binding on patent applicants in the United States, where public disclosure of a patented product and associated data may preclude patentability after time.

¹⁴³ KUANPOTH, *supra* note 125, at 16–17.

¹⁴⁴ *Id.*

¹⁴⁵ *Id.* at 15; OXFAM INT'L, *supra* note 20, at 19.

¹⁴⁶ See AHEARN & MORRISON, *supra* note 89, at 2 ("By eliminating U.S. tariff and non-tariff barriers to Thai exports, an FTA could help increase the competitiveness and market share of Thai products in the U.S. market.").

refers generally to an unspecified increase in U.S. investment in Thailand.¹⁴⁷

A 2003 study of the U.S.-Thailand FTA by the Thailand Development Research Institute ("TDRI"), using a computable general equilibrium model, predicted that the FTA could lead to a 5.41% increase in exports from Thailand to the United States.¹⁴⁸ However, analysis has indicated that while exports may increase, U.S. goods, particularly meat, dairy, and some agricultural products, would probably still have an advantage over similar products from Thailand.¹⁴⁹ The TDRI study also found that the FTA would lead to a 1.34% increase in real GDP.¹⁵⁰ These numbers do not indicate strong economic results for Thailand under the FTA. The TDRI study stated that if the GDP growth took three years to occur, the additional growth in the economy from the FTA would be just over one-half percent annually, and thus would not justify a rush to enter such an FTA.¹⁵¹ This level of growth is of the same order of magnitude as projected drops in real GDP caused by HIV/AIDS in heavily afflicted countries.¹⁵² The similarity between projected gains and losses is significant because the FTA itself curbs a nation's ability to stem HIV/AIDS losses. An FTA thus not only provides minimal gains but also eliminates options to address a health problem already sapping national economic development. While the economic losses attributed to HIV/AIDS cannot be eliminated entirely by preserving IP flexibilities, these policy options will be a crucial element of a comprehensive policy solution. Further, HIV/AIDS-based GDP losses may surpass current estimates if Thailand lacks the IP flexibilities necessary to craft an effective solution to the problem. GDP gains from an FTA would not likely rise in proportion to these additional losses.

¹⁴⁷ See *id.* ("Thailand also does not want to be excluded from FTA benefits the U.S. has negotiated with other countries, particularly the potential of an FTA to increase U.S. investment in Thailand.").

¹⁴⁸ THAILAND DEVELOPMENT RESEARCH INSTITUTE, A STUDY ON THE IMPACTS OF THAILAND-US FREE TRADE AGREEMENT 30 (2003), available at <http://www.info.tdri.or.th/reports/published/final.zip> [hereinafter TDRI REPORT].

¹⁴⁹ KUANPOTH, *supra* note 125, at 12.

¹⁵⁰ TDRI REPORT, *supra* note 148, at 30.

¹⁵¹ *Id.* at 33 ("Even with the TDRI CGE model the real economic expansion following the FTA is merely 1.34 percent. If the impacts take three years to fully realize, the additional growth rate from the FTA is less than half a percentage point annually. There seems to be no cause then for rushing the negotiation process.").

¹⁵² See *supra* Section 5.2.

6.3. SACU HIV/AIDS Treatment Programs and Pharmaceuticals

By necessity, several SACU countries have addressed the severe AIDS infection rates with ARV programs. Botswana, a leader in recognizing the problem posed by AIDS and in offering treatment, began offering ARVs through a public healthcare system in December 2001.¹⁵³ The public health system was providing 17,000 people with ARVs by October 2004,¹⁵⁴ and over 54,000 people were getting ARVs by September 2005.¹⁵⁵ The Namibian government initiated an ARV program in 2003,¹⁵⁶ and was providing free ARVs to roughly 24,000 people by 2006.¹⁵⁷ South Africa, the SACU country with the most people living with HIV/AIDS, initiated an ARV program in 2003.¹⁵⁸ By October 2006, about 265,000 people were receiving free ARVs.¹⁵⁹

Lesotho and Swaziland have been less successful. Lesotho has not enacted any substantial public program providing ARVs. The pharmaceutical company Bristol-Myers Squibb did set up an ARV program,¹⁶⁰ but the WHO found that in December 2005, only 8,400 of the 58,000 people needing ARV treatment were receiving it.¹⁶¹ In Swaziland, 13,006 of the 42,000 people needing ARVs receive them.¹⁶²

¹⁵³ Tenu Avafia, *The Potential Impact of US-SACU FTA Negotiations on Public Health in Southern Africa* 13 (Trade Law Centre for Southern Africa, Working Paper No. 6/2004, 2004), available at http://www.bilaterals.org/article.php3?id_article=1357.

¹⁵⁴ *Id.* It is notable that 17,000 people are enrolled in Botswana's public ARV program, but this number is still far fewer than the 300,000 infected people in the country. *Id.*

¹⁵⁵ *Botswana's ARV Programme an Example to Others*, MAIL & GUARDIAN ONLINE, Nov. 30, 2005, <http://www.mg.co.za/articlePage.aspx?articleid=258115>.

¹⁵⁶ Avafia, *supra* note 153, at 14.

¹⁵⁷ *Namibia: Reaching Targets Despite Great Obstacles*, PLUSNEWS, Oct. 30, 2006, <http://www.plusnews.org/Report.aspx?ReportId=62634>.

¹⁵⁸ Avafia, *supra* note 153, at 14.

¹⁵⁹ Nawaal Deane, *ARV Targets Fall Short*, HEALTH-E, Dec. 1, 2006, <http://www.health-e.org.za/news/article.php?uid=20031552>.

¹⁶⁰ Avafia, *supra* note 153, at 15.

¹⁶¹ WORLD HEALTH ORG., LESOTHO: SUMMARY COUNTRY PROFILE FOR HIV/AIDS TREATMENT SCALE-UP 1 (2005), available at http://www.who.int/hiv/HIVCP_LSO.pdf.

¹⁶² WORLD HEALTH ORG., SWAZILAND: SUMMARY COUNTRY PROFILE FOR HIV/AIDS TREATMENT SCALE-UP 1 (2005), available at http://www.who.int/hiv/HIVCP_SWZ.pdf.

6.4. The U.S.-SACU FTA

The terms of the proposed U.S.-SACU FTA with respect to intellectual property are very similar to those in the U.S.-Thailand FTA. The FTA includes limitations on compulsory licenses and access to test data that are now standard fixtures of U.S. FTAs, and requires SACU countries to adopt U.S. standards of patentability and patent duration. In early 2006, it became apparent that the U.S.-SACU negotiations were unlikely to yield a completed FTA due to the intractable stance of the United States.¹⁶³ However, SACU is still discussing a series of scaled back trade talks,¹⁶⁴ so it will remain important for the SACU countries to bear pharmaceutical access in mind as they evaluate any trade agreements.

The analysis that exists for the U.S.-SACU FTA shows fairly modest economic gains for the SACU countries. One study estimated that the FTA would produce a one percent rise in GDP for the SACU countries.¹⁶⁵ The study also found that increases in U.S. imports from SACU countries would be small.¹⁶⁶ The study also concluded that benefits from increased U.S. investment in SACU countries would be small.¹⁶⁷ The study concluded that a unilateral or multilateral trade regime would be more economically beneficial for SACU than the bilateral U.S.-SACU FTA.¹⁶⁸ Perhaps more importantly, possible GDP losses attributable to HIV/AIDS, discussed in Section 5.2, either equal or surpass potential gains from the U.S.-SACU FTA.

¹⁶³ See "Inflexible" U.S. Threatens Southern Africa Free-Trade Deal, TRADE LAW CENTRE FOR SOUTHERN AFRICA, Mar. 31, 2006, <http://www.tralac.org/scripts/content.php?id=4703> (discussing how the inflexibility of the United States on a variety of trade-related issues led SACU to be reluctant to complete an FTA).

¹⁶⁴ Terence Creamer, SACU-U.S. to Pursue Scaled-Back Trade Talks After FTA Process Ceases, POLITY (S. Afr.), Nov. 21, 2006, http://www.polity.org.za/article.php?a_id=98063.

¹⁶⁵ Drusilla K. Brown, Kozo Kiyota & Robert M. Stern, *An Analysis of the U.S.-SACU FTA Negotiations* 19 (Ford Sch. of Pub. Policy, Univ. of Mich., RSIE Discussion Paper No. 545, 2006), available at <http://www.fordschool.umich.edu/rsie/workingpapers/Papers526-550/r545.pdf>.

¹⁶⁶ See *id.* at 19-20 (stating that export increases are small in percentage terms, and that the largest gains would be in textiles and apparel, trade and transport services, and other private and government-related services).

¹⁶⁷ *Id.* at 21.

¹⁶⁸ *Id.* at 22.

7. COMPARISONS TO EXISTING U.S. FTAS

The United States completed a TRIPS-plus FTA with Jordan in 2001 and another with Australia in 2004. Because these FTAs have been in force for several years, more rigorous economic predictions and even some empirical data exist showing the costs and benefits of the FTAs. These data include the effect of the FTAs on drug pricing, on the time it takes for generics to come to market, and on domestic pharmaceutical production. Comparisons of the pharmaceutical sectors in Jordan and Australia to those in Thailand and the SACU countries, as well as economic analysis of the U.S.-Jordan and U.S.-Australia FTAs, help give a performance baseline of the likely economic impacts and drug access that can be expected for Thailand and the SACU countries under the proposed U.S. FTAs.

7.1. *Australia*

7.1.1. *The Australian Pharmaceutical Sector and the Pharmaceutical Benefits Scheme*

While Australia's pharmaceutical sector is not nearly as developed as that of the United States, it far exceeds pharmaceutical sectors in most developing countries. Australia has over 120 pharmaceutical companies located in the country, including both domestic and foreign-owned companies.¹⁶⁹ These firms all perform research and development ("R&D") and the workforce is described as "highly skilled and productive."¹⁷⁰ Globally the Australian sector is relatively small, comprising only one percent of total global pharmaceutical sales,¹⁷¹ yet is growing fairly rapidly. Despite this, Australia still imports far more than it exports—in 2002 Australia imported pharmaceuticals totaling U.S. \$3 billion while it exported only \$1.2 billion.¹⁷² R&D spending increased from \$26.6 million in 1987–1988 to \$196 million in 1999–

¹⁶⁹ MONIQUE ROOS, PHARMACEUTICAL INDUSTRY: AUSTRALIA (2003), <http://strategis.gc.ca/epic/site/imr-ri.nsf/fr/gr114412f.html>.

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² *Id.* (stating that Australia's pharmaceutical imports of U.S. \$3 billion came primarily from the United States, the United Kingdom, Germany, and Switzerland).

2000,¹⁷³ and Australia's share of exports (as a percentage of OECD-15 total pharmaceutical exports) has risen from 0.6% in 1980 to 1.7% in 2000.¹⁷⁴

Like Thailand and the SACU countries, Australia has used a governmental body to address drug-pricing issues. The Pharmaceutical Benefits Advisory Committee ("PBAC") investigates whether a new drug is cost-effective at the price the producing company charges.¹⁷⁵ After investigation by the PBAC, the Pharmaceutical Benefits Scheme ("PBS") does not seek the lowest possible price, but rather it pays what it believes is a fair price for the drug.¹⁷⁶ Because the PBS does not seek to minimize costs, it has been criticized for not taking maximum advantage of the availability of generic products.¹⁷⁷ However, the results show that the PBS has been effective. In 2003 the Australia Institute estimated that for high-cost drugs, the PBS showed savings of roughly 35% by the fourth year after competing generic drugs were introduced.¹⁷⁸ The PBS is widely regarded as being one of the most successful governmental pharmaceutical distribution and price-reduction systems in the world.¹⁷⁹

Both the features of the Australian pharmaceutical industry described above and the success of the PBS demonstrate several key points about the sector. First, Australia has an established

¹⁷³ *Id.* (indicating that increased R&D spending has been a key factor leading to growth of the Australian pharmaceutical industry).

¹⁷⁴ George Messinis, *The Australian Pharmaceutical Industry and its Global Context* 26 fig.21 (Pharmaceutical Indus. Project: Equity, Sustainability and Indus. Dev., Working Paper No. 7, 2002), available at http://cfes.com/documents/pharma/07-Aust_Pharma_Ind.PDF.

¹⁷⁵ See Peter Drahos et al., *Pharmaceuticals, Intellectual Property and Free Trade: The Case of the U.S.-Australia Free Trade Agreement*, 22 PROMETHEUS 243, 244 (2004) [hereinafter *Pharmaceuticals, Intellectual Property and Free Trade*] ("The PBAC judges whether a new drug is cost-effective . . . by comparing it (reference pricing) with an existing therapy (usually another drug). If the PBS is to pay a higher price for the new drug than for the old, Section 101 of the *National Health Act* requires that the committee be convinced that the new one is more effective, safer, or both.").

¹⁷⁶ See *id.* at 246 ("In order to obtain [a fair] price the PBS through its committees of experts aggregates information about a drug and then develops a sophisticated evaluation of a drug's clinical worth.").

¹⁷⁷ See *id.* at 251 (stating that the PBS system needs reform because it does not take maximum advantage of generic drug competition).

¹⁷⁸ *Id.*

¹⁷⁹ See *id.* at 243 (stating that Australia's PBS is "regarded by many as representing the world's best practice").

pharmaceutical industry comprising both foreign and domestic firms, all of which conduct R&D activities in the country. Second, while Australia is a net pharmaceutical importer, it does export pharmaceutical products, and its capacity in this area is growing. Finally, Australia has a generic drug industry with sufficient capacity to facilitate the PBS. These features distinguish it greatly from most developing countries.

7.1.2. *The Australia-U.S. FTA*

It is logical to think that because Australia had the fifteenth largest economy in the world at the time the Australia-U.S. FTA ("AUSFTA")¹⁸⁰ was completed,¹⁸¹ the United States would have offered Australia more favorable terms in its FTA than those the United States has offered to developing countries. However, the AUSFTA embodies most of the same key features as the proposed Thailand agreement. For example, compulsory licenses are limited to the same three circumstances—to remedy anticompetitive practices, in cases of public non-commercial use, and in circumstances of national emergency.¹⁸² The FTA eliminates the experimental use exception, allowing only the early working exception to apply to production of competing pharmaceutical products.¹⁸³ Like the Thai FTA, the AUSFTA blocks registration of generics for at least five years.¹⁸⁴

Based on its limitations of generic drugs, the Australia Institute estimated that the AUSFTA would delay release of generics by an average of twenty-four months.¹⁸⁵ The study analyzed five brand-name drugs that would soon have generic competition, and

¹⁸⁰ U.S.-Austl. Free Trade Agreement, May 18, 2004, 118 Stat. 919 [hereinafter AUSFTA].

¹⁸¹ Drahos et al., *Pharmaceuticals, Intellectual Property and Free Trade*, *supra* note 175, at 243.

¹⁸² AUSFTA, *supra* note 180, art. 17.9(7).

¹⁸³ *Id.* art. 17.9(6).

¹⁸⁴ *Id.* art. 17.10(1)(a).

¹⁸⁵ See BUDDHIMA LOKUGE, THOMAS ALURED FAUNCE & RICHARD DENNISS, THE AUSTRALIA INSTITUTE, A BACKDOOR TO HIGHER MEDICINE PRICES? INTELLECTUAL PROPERTY AND THE AUSTRALIA-US FREE TRADE AGREEMENT 14 (2003), available at <http://cgkd.anu.edu.au/menus/PDFs/Patents%20and%20FTA%20final.pdf> (giving the "central case," which the Institute felt was likely to be a conservative estimate of the negative impact of the FTA).

calculated that the delay in release of the generics would result in \$1.12 billion in lost savings to PBS from 2006 to 2009.¹⁸⁶

One method of estimating the implications of an FTA on drug prices is to compare the prices in the nations subject to the trade agreement. For example, leading up to the AUSFTA, a variety of studies related Australian drug prices to comparable ones in the United States. One compared PBAC costs in Australia to the costs under the U.S. Federal Supply Schedule ("FSS"), which lists prices paid for pharmaceuticals by a variety of U.S. federal agencies.¹⁸⁷ This study found that drug purchases by institutional buyers in the United States, as listed by FSS, cost roughly 1.84 to 2.49 times more than Australia's PBAC prices.¹⁸⁸

7.2. Jordan's Pharmaceutical Sector and the U.S.-Jordan FTA

Jordan, which signed a TRIPS-plus FTA with the United States in 2001, provides another point of comparison. The pharmaceutical industry in Jordan is growing, showing an increase from \$77 million in total domestic production in 1990 to over \$250 million in 2000.¹⁸⁹ Despite this, Jordan's production still lags behind more developed countries, such as Australia. In 2003, Jordan's pharmaceutical exports were over \$203 million,¹⁹⁰ around one sixth of Australia's 2002 exports. In addition, the Jordanian sector is characterized by "limited capital resources and weak R&D

¹⁸⁶ *Id.* The Centre for International Economics also released a study of the proposed impacts of the AUSFTA, but reached different conclusions. See CTR. FOR INT'L ECON., ECONOMIC ANALYSIS OF AUSFTA 60 (2004), available at http://www.thecie.com.au/content/publications/CIE-economic_analysis_ausfta.pdf ("The pharmaceutical measures outlined in AUSFTA are likely to have a minimal impact on the PBS."). This study dismissed past estimates of costs under the PBS associated with the FTA, but gave no compelling reasons for doing so, other than to say that the studies were completed before adoption of the FTA's final terms. *Id.* The study concluded, again with little to no justification, that the AUSFTA would have "no significant net effect on the PBS" and did not include the PBS in its economic model of the FTA's overall effects. *Id.*

¹⁸⁷ See Drahos et al., *Pharmaceuticals, Intellectual Property and Free Trade*, *supra* note 175, at 252 ("The [U.S. Federal Supply Schedule] lists the prices paid for pharmaceuticals purchased by the US Department of Veterans Affairs and other Federal agencies—large institutional buyers with bulk purchasing powers comparable to the PBS.").

¹⁸⁸ *Id.*

¹⁸⁹ El-Said & El-Said, *supra* note 83, at 70.

¹⁹⁰ *Id.*

capacity,”¹⁹¹ leading to a limited ability to innovate and create new pharmaceutical products.

The Jordanian FTA with the United States embodies the common features of IP protection included in the other FTAs discussed in this Comment. This includes tying approval for Jordanian pharmaceutical exports to compliance with U.S. regulatory requirements and expanding protection for new uses of previously patented drugs.¹⁹² In 1995, the Jordanian Industrial Development Bank (“IDB”) published a study that found strengthening IP rights would harm local production, in terms of both investment and output; decrease local production, and thus employment levels; increase drug imports and decrease exports; and increase pharmaceutical prices.¹⁹³ Despite U.S. predictions of trade expansion, the results of the FTA for Jordan’s pharmaceutical sector have so far been much closer to the results anticipated by the 1995 IDB study.

In 2003, two years after the U.S.-Jordan FTA was signed, a Jordanian pharmaceutical producer described the country’s development strategy as “branded-generic,” which he explained means that producers “‘search for the formula on the internet . . . and then we produce it. Some copy the formula literally but most modify it a little bit then produce it under a different name’”¹⁹⁴ Producers pursue this strategy as long as the drugs are no longer protected by patent, indicating the complete absence of R&D and innovation potential. Producers essentially produce only drugs that have come off patent after their twenty-year term of protection expires, severely limiting access to new drugs.

Contrary to the promises often made during FTA negotiations that foreign nations will invest directly in building capacity in-country, not one multinational pharmaceutical company has sought to establish facilities in Jordan, preferring to export pharmaceutical products or license production.¹⁹⁵ This is in spite of the fact that foreign investment in Jordan in general has been

¹⁹¹ *Id.* at 72.

¹⁹² *Id.* at 69.

¹⁹³ *See id.* at 72 (citing INDUS. DEV. BANK, STUDY FOR THE DEVELOPMENT OF THE PHARMACEUTICAL INDUSTRY IN JORDAN (1995)).

¹⁹⁴ *Id.* at 72–73. (quoting a June 2003 interview with Amman, a local pharmaceutical provider).

¹⁹⁵ *See id.* at 73 (“So far, not even a single multinational pharmaceutical firm has opted to serve the Jordanian market by establishing fully owned production facilities there.”).

rising since 1997 due to privatization, long before Jordan adopted stronger IP rights.¹⁹⁶ As a result, drug imports have been rising steadily, from \$58 million in 1990 to more than \$203 million in 2003,¹⁹⁷ and evidence suggests that prices have also increased.¹⁹⁸ Finally, the share of local firms in the industry decreased to 35% in 2000, down from a previous high of 45%.¹⁹⁹ These data show that the FTA Jordan signed does not correlate to a better ratio of pharmaceutical exports to imports, to a more developed domestic pharmaceutical research capacity, or to a greater percentage of local firms in the domestic industry.

7.3. Implications for the U.S.-Thailand and U.S.-SACU FTAs

The preceding analysis of the AUSFTA and U.S.-Jordan FTA demonstrates that even in developed countries, TRIPS-plus treaties can have a significant negative impact on pharmaceutical prices, and that the effects are even more pronounced in countries with less developed pharmaceutical sectors. While studies predict that Australia will experience slower time-to-market and increased prices for generic drugs as a result of the AUSFTA, the industry is growing nonetheless, and has increased its percentage of exports. This is in stark contrast to the results for Jordan, which now has a pharmaceutical sector that has little R&D capacity and essentially produces only medicines that have come off patent. This divergence of outcomes for Australia and Jordan illustrates the importance of several key factors in predicting the impact of restrictive IP rights on a country's pharmaceutical sector. These factors include:

- (1) the strength of domestic producers relative to foreign producers in a country's pharmaceutical industry;
- (2) the country's level of R&D capacity;
- (3) a country's ability to produce generic drugs; and
- (4) a country's strength as a pharmaceutical exporter.

¹⁹⁶ *Id.* at 71.

¹⁹⁷ *Id.* at 73.

¹⁹⁸ *See id.* ("Anecdotal evidence also suggests that the price of medicine in Jordan, which is largely demand inelastic, has risen sharply in recent years, particularly the prices of imported drugs and that which is produced locally but under international licensing agreements.").

¹⁹⁹ *Id.*

The stronger a country is in the areas mentioned above, the more able it will be to take advantage of strong IP protection in fostering its own domestic industry and production capacity. Countries that are weak in these areas will not be able to profit from strong IP rights, and will likely lose out to foreign countries that are more successful in R&D and exportation. These foreign nations will use the newly enhanced IP regimes as a tool to increase exports, but may have little incentive to transfer technology to the FTA host country. The likely end result for the developing countries is a diminished ability to use IP flexibilities to control drug prices or provide broad access, but no corresponding growth of their own pharmaceutical industry. Analysis in terms of these factors, and comparison to both Australia and Jordan, reveal that Thailand and the SACU countries lack the strength in R&D, domestic production, and drug exportation to benefit from IP-restrictive FTAs.

In 2005, Thailand had 162 firms that manufactured modern pharmaceutical products,²⁰⁰ but no firms in Thailand, either foreign or local, performed research and development seeking to develop new drugs.²⁰¹ Due to the lack of domestic R&D and production, Thailand also imports roughly 95% of the chemical compounds needed for drug production, adding to the nation's dependence on foreign countries for access to medicine.²⁰² As discussed previously, generic drugs have been crucial to AIDS treatment efforts in Thailand. While branded drugs produced by multinational companies still enjoy a healthy market share (35%), Thailand depends heavily on generic drugs.²⁰³ A system of IP rights that decreases Thailand's ability to produce or import generics will severely hamper its access to medicines, and thus its programs to fight AIDS. The World Bank reached the same conclusion, noting that while Thailand may be tempted to enter into a bilateral FTA with the United States that included limitations on compulsory licensing, doing so would be very detrimental to Thailand's ability to treat AIDS.²⁰⁴

²⁰⁰ KUANPOTH, *supra* note 125, at 24.

²⁰¹ *Id.* at 25.

²⁰² *Id.* at 26.

²⁰³ See *id.* at 35-36 (concluding that the characteristics of the Thai pharmaceutical market, coupled with branded drug company marketing strategies, cause unnecessarily high consumption of non-essential drugs, strong reliance on branded drugs, and high drug prices).

²⁰⁴ REVENGA ET AL., *supra* note 131, at 169 ("Because Thailand stands to gain a

The research pharmaceutical industry is somewhat more developed in southern Africa than in Thailand, but key limitations exist compared to Australia. For example, of the five SACU nations only South Africa has a well-established generic pharmaceutical manufacturing industry, and no other country in the region has the expertise to establish such a multi-firm industry.²⁰⁵ Thus, South Africa is a potential pharmaceutical exporter, but the other SACU countries have very limited capacity to produce their own ARVs at affordable prices. Unlike Thailand, several key research pharmaceutical companies have facilities in southern Africa,²⁰⁶ although it is unclear whether the presence of offices in the region translates to greater in-country knowledge that can be used to produce cost-effective AIDS drugs. Without the ability under the FTA to require local production, it is unlikely that any increased foreign investment in the region that results from an FTA would lead to technology transfer or enable development of a generics industry.

Analysis of the key factors discussed above shows that Australia is more developed, both overall and specifically in the pharmaceutical field, than either Thailand or the SACU countries. It has greater national R&D capacity and the ability to produce new drugs, as well as the ability to produce inexpensive generic drugs quickly. It also has been gaining strength as an exporter, and at least some of the pharmaceutical companies in the country are domestic. Thailand and the SACU countries, both of which lack a true research pharmaceutical industry, are thus much more similar to Jordan than they are to Australia. Both have more limited ability than Australia to develop new drugs and generics quickly, if at all. As such, the delays in rollout and increased cost of generic drugs that experts have predicted for Australia (delay of generics by twenty-four months and lost savings of \$1.1 billion

great deal from bilateral agreements to reduce trade barriers with trading partners such as the United States, the Royal Thai government may be tempted to relinquish its rights to grant compulsory licenses for AIDS drugs in exchange for proffered trade advantages. The report finds that the cost of such concessions would be large.”).

²⁰⁵ Tenu Avafia et al., *The Ability of Select Sub-Saharan African Countries to Utilise TRIPs Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries* 3 (Trade Law Ctr. for S. Afr., Working Paper No. 12/2006, 2006), available at http://www.tralac.org/pdf/20061002_Avafia_TRIPsandCompetitionLaw.pdf.

²⁰⁶ *Id.*

over four years) are likely to be more pronounced in Thailand and the SACU countries as a result of an FTA. These countries are also likely to experience the increased imports and erosion of existing domestic industry that Jordan saw following completion of its FTA. Contrary to claims by developed countries, similarities of the industry structure in these countries to that in Jordan indicate that even if FTAs do lead to higher FDI, this will not build domestic capacity to provide greater access to cheaper AIDS drugs.

Due to their inability to mitigate the risks of a TRIPS-plus FTA through the existence of a robust domestic pharmaceutical industry, Thailand and the SACU countries will likely be worse off than Australia and Jordan if they sign the proposed FTAs. These nations simply lack the capacity to turn restrictive IP regimes to their advantage, and would lose out to foreign nations who have greater strength to make use of the TRIPS-plus framework. The end result will be diminished success of AIDS treatment programs, which all rely heavily on provision of generic ARV drugs. Given the severe economic and social costs of AIDS in these countries, discussed in Section 5.2, the harm from an FTA is likely to extend not only to the pharmaceutical sector, but also to the national economy as a whole.

8. CONCLUSION

Developing countries face great pressure to sign FTAs, often under threat of trade sanctions, but many factors indicate that they should not enter into these agreements. The benefits are more modest than developed countries predict, and developing countries constrain their policy options greatly by signing these FTAs, especially in the pharmaceutical field. In countries with a significant HIV/AIDS problem, the economics are even less favorable due to the costs of the disease and the diminished options for treatment that the FTAs cause. In the case of Thailand and the SACU countries, a comparison of the costs of AIDS to the anticipated benefits of the FTA indicates that the economic and social costs outweigh the benefits, and these countries have done well to move away from FTAs with the United States.

In the future, developing countries, especially those battling HIV/AIDS epidemics, must keep their options open to enable access to essential medicines. The flexibilities in the TRIPS agreement, such as compulsory licenses, parallel imports, and the ability to set standards for patentability and patent terms, are key

tools in fighting HIV/AIDS. Developing countries must preserve their ability to use these tools. While trade expansion is an important economic goal, developing countries should not sign a TRIPS-plus FTA until they either achieve a degree of success in their fight against AIDS, or develop a significant domestic, R&D-based pharmaceutical sector that actually can benefit from stronger intellectual property rights.